FEB 2 6 2004

K033689

PREMARKET NOTIFICATION 510(K) SUMMARY

Sponsor:	Integration Diagnostics Ltd. Gamlestadsvagen 3 B 415 02 Goteborg SWEDEN Telephone: +46-31-340 82 51 Fax +46-31-41 31 15 Contact: Anders Petersson
Manufacturer:	Same as above
Registration Number:	3004070020
Contact Person:	Trish Landry or Russ Pagano M Squared Associates, Inc. 719 A Street, NE Washington DC 20002 Telephone: 202-546-1262 Fax: 202-546-3848 E-mail: tlandry@msquaredassociates.com
Trade Name of Device:	Osstell Mentor
Common Name:	Dental Implant Stabilizer
Classification name:	Handpiece, Direct Drive, AC-Powered
Product Code:	EKX
Regulation Class:	I
Regulation Number:	§870.4200

Device Description: The Osstell Mentor Resonance Frequency Analyzer (RFA) is an updated version of the Osstell™ (K003714), the system designed to measure dental implant stability in the oral cavity and craniofacial region. Similar to K003714, the Osstell Mentor is a portable, handheld instrument that involves the use of the noninvasive technique, Resonance Frequency Analysis. The updated system involves the use of a Smartpeg (aluminum rod) attached to the dental implant by means of a screw. The Smartpeg is excited by a magnetic pulse from the measurement probe on the handheld instrument. The resonance frequency, which is the measure of implant stability, is calculated from the response signal. Results are displayed as the Implant Stability Quotient (ISQ). The ISQ is a measurement of the stability of the implant and is derived from the resonance frequency value obtained from the Smartpeg.

Indications for Use: The Osstell Mentor RFA is indicated for use to measure the stability of dental implants in the oral cavity and craniofacial region.

Basis for Substantial Equivalence

Predicate Device: Osstell™

The Osstell Mentor is substantially equivalent to the previous version of the device, the Osstell (K003714), for the following reasons:

- The Osstell Mentor has the same indication for use as the Osstell cleared by FDA under 510(k), K003714.
- The functioning of the Osstell Mentor and the Osstell is similar in that both devices use a form of vibration to assess implant stability.
- The Osstell Mentor has no unique or new applications, indications or functions.
- The Osstell Mentor raises no new issues with respect to safety or effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 2004

Integration Diagnostics Limited
C/O Ms. Tish Landry
Senior Consultant
M Squared Associates, Incorporated
719 A Street NE
Washington, DC 20002

Re: K033689
Trade/Device Name: Osstell Mentor RFA
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: February 18, 2004
Received: February 19, 2004

Dear Ms. Landry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

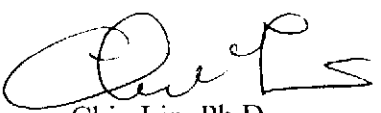
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

co.nply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033689

Device Name: Osstell™ Mentor

Indications For Use: The Osstell Mentor is indicated for use in measuring the stability of implants in the oral cavity and craniofacial region. The Osstell Mentor can add important information to the evaluation of implant stability and can be used as part of an overall treatment evaluation program. The final implant treatment decisions are the responsibility of the surgeon.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulloy for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033689